

Evaluating the Implementation of Rapid HIV Testing for Women with Undocumented Status at Labor and Delivery at North Carolina Facilities

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A Master's Paper submitted to the faculty of
the University of North Carolina at Chapel Hill
in partial fulfillment of the requirements for the
degree of Master of Public Health in the
Public Health Leadership Program

Chapel Hill

2013

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Date

Acknowledgements:

I would like to thank the following persons for taking the time to provide their expertise and support in the development of this survey:

Lynne Sampson – NC Department of Health and Human Services

Lisa Rahangdale – UNC Chapel Hill Women’s Hospital

Coleen Cunningham - Duke University Medical Center

Elizabeth Livingston – Duke University Medical Center

Abstract

Objectives: Documenting HIV status for women in labor is key in the prevention of perinatal transmission from mother to child. Rapid HIV testing at intake for Labor and Delivery (L & D) allows for a quick result and the opportunity to implement short course antiretroviral therapy to the mother during labor to interrupt HIV transmission. This survey was designed to evaluate how well the activity of Rapid HIV testing of pregnant women with undocumented status at L & D has been operationalized by North Carolina (NC) medical facilities in accordance with NC law. For women presenting at L & D, these practices should include confirming HIV status, Rapid HIV testing if status is unavailable, and referral of positive patients and newborns to an HIV disease specialist. In addition, facilities should have established formal policies to ensure that Rapid HIV testing is uniformly conducted for women with undocumented status at L & D.

Design / Methods: This survey was administered online to Nurse Managers or Nurse Supervisors at NC facilities that had at least one birth recorded in 2010. Each facility was contacted by phone and requested to participate in the survey. Of the 94 facilities identified as having had a birth in 2010, a total of 61 facilities had respondents that completed the survey.

Results: The main findings were that 93% of surveyed facilities indicated they do review a woman's prenatal record to confirm previous HIV testing. However, only 72% of respondents selected that they would always perform an HIV test if previous testing history is unavailable. Additionally, based on the lengths of time respondents indicated for

the return of test results (14% said greater than 12 hours), many facilities do not appear to be utilizing Rapid HIV testing. Respondents selected perceived barriers to testing such as lack of patient consent and inadequate time to perform a test that indicate they aren't fully cognizant of NC law. Approximately 70% of respondents indicated their facility had formal policies regarding HIV testing. Some differences were noted between facilities based on geographical location as well as number of births per facility.

Conclusions: Based on the survey results, Rapid HIV testing is not uniformly conducted in NC facilities for women with undocumented status at L & D. In order to achieve uniform standard facility practices, the NC Department of Health & Human Services (NC DHHS) should at a minimum develop a best practices document that can be distributed to facilities to educate their staff on their responsibilities under the law particularly in the utilization of Rapid HIV testing. Ensuring the availability of Rapid HIV tests at all facilities is also recommended.

Introduction

The most common route of HIV infection in children is perinatal transmission, or transmission from mother to child. Public health efforts can virtually eliminate perinatal transmission of HIV. An HIV positive woman who is treated with the appropriate antiretroviral therapy will have less than a 1% chance of transmitting the virus to her baby (Centers for Disease Control and Prevention, 2012). A significant barrier to eliminating perinatal HIV transmission is an undocumented HIV status for pregnant women at Labor and Delivery (L & D). Approximately 30-40% of infants perinatally infected are born to a woman who does not know her HIV status (Levison, Williams, Moore, McFarlane, & Davila, 2012). An unknown HIV status at L & D represents a missed opportunity to reduce the likelihood of perinatal transmission, where even a short course of antiretroviral therapy can be successful. Rapid HIV tests that are administered at L & D can provide preliminary test results in less than 20 minutes, while traditional EIA tests can take up to 48 hours (Li & Sax, 2010). A standard EIA test is not likely to provide a result in time for an intervention during L & D.

In 2006, the Centers for Disease Control and Prevention (CDC) updated the recommendations for HIV testing pregnant women to include opt-out HIV testing as part of the routine universal prenatal screening tests and repeat testing in the 3rd trimester in areas with elevated rates of HIV, as well as Rapid HIV testing at L & D for women not screened during pregnancy (Branson et al., 2006). As of 2009, HIV testing laws in North Carolina require L & D providers to perform a Rapid HIV test on all women with undocumented status, regardless of consent, unless testing endangers the woman. This

law was updated in 2007, but providers had until 2009 to implement Rapid HIV testing. Although the law does mandate testing at L & D, note that this is a last effort to interrupt perinatal transmission. The initial purpose of the law is to require providers to offer women HIV testing as part of prenatal care. The law states:

“Every pregnant woman shall be offered HIV testing by her attending physician at her first prenatal visit and in the third trimester. The attending physician shall test the pregnant woman for HIV infection, unless the pregnant woman refuses to provide informed consent pursuant to G.S. 130A-148(h). If there is no record at labor and delivery of an HIV test result during the current pregnancy for the pregnant woman, the attending physician shall inform the pregnant woman that an HIV test will be performed, explain the reasons for testing, and the woman shall be tested for HIV without consent using a rapid HIV test unless it reasonably appears that the test cannot be performed without endangering the safety of the pregnant woman or the person administering the test. If the pregnant woman cannot be tested, an existing specimen, if one exists that was collected within the last 24 hours, shall be tested using a rapid HIV test. The attending physician must provide the woman with the test results as soon as possible. However, labor and delivery providers who do not currently have the capacity to perform rapid HIV testing are not required to use a rapid HIV test until January 1, 2009.” (State of North Carolina, 2007)

A number of studies have been done that look at barriers to HIV testing and use of Rapid HIV tests at L & D. A study by Anderson et al (2002) found that providers’ perceptions of a patient’s risk for HIV influenced their decision to conduct an HIV test. This study also found that rates of Rapid HIV testing in L & D were fairly low (Anderson, Carlson, Anderson, Hawks, & Schulkin, 2002). Another finding of the study indicated that providers might be confused about their states’ HIV testing requirements (Anderson, Carlson, Anderson, Hawks, & Schulkin, 2002). A study of New Jersey hospitals found inconsistencies in HIV testing at L & D, with Rapid HIV testing not always available and not always used if available (Kelley, Paul, Vali, Caruso, Martin, & Fleming, 2011).

No formal study or facility review has previously been undertaken to determine if North Carolina facilities have implemented uniform testing policies in accordance with the 2007 law. As recently as 2010 however, the North Carolina Pregnancy Risk Assessment Monitoring System (NC PRAMS) survey indicated that 11.6% of surveyed women asked if they had an HIV test during their most recent pregnancy answered 'no' with another 11% reporting they did not know if they were tested (North Carolina Center for State Health Statistics, 2010). Almost 20% of women surveyed who indicated they had prenatal care said their provider did not talk to them about getting tested for HIV (North Carolina Center for State Health Statistics, 2010).

2010 North Carolina Pregnancy Risk Assessment Monitoring System Survey Results

HIV

At any time during your most recent pregnancy or delivery, did you have a blood test for HIV (the virus that causes AIDS)?

Demographic Groups	Total Respond.#	No			Yes			Unknown		
		N	%	C.I.(95%)	N	%	C.I.(95%)	N	%	C.I.(95%)
Total	968	128	11.6	9.5-14.0	736	77.4	74.3-80.3	104	11.0	8.9-13.5

Figure 1. 2010 NC PRAMS Survey (North Carolina State Center for Health Statistics, 2010)

This survey was developed in order to provide a baseline assessment of current facility practices regarding HIV testing of women at L & D, and to determine what steps need to be taken to ensure uniform statewide practices. Specific survey objectives include determining: 1) the availability of documentation of previous HIV testing; 2) whether not a Rapid HIV test is administered, when an HIV test is administered, and how the test is processed; 3) if HIV+ women and babies are referred to an HIV disease specialist; and 4) if

facilities have formal policies in place on conducting HIV testing at L & D. In order to avoid response bias, the survey does not mention the NC law, the 2009 deadline for implementation of Rapid HIV testing, or Rapid HIV tests specifically. Instead survey questions were designed to indirectly determine if facilities are aware of the law and the availability of Rapid HIV testing. Approval for the administration of the survey was obtained from UNC's Institutional Review Board (IRB) based on participant confidentiality, so participant responses are not linked with the facility name. Analysis was conducted in a manner as to ensure that facilities are not identifiable.

Methods

Participants

A request was made to the State Center for Health Statistics (SCHS), a branch of NC DHHS, to provide a dataset that identified all facilities that recorded at least one birth in 2010, which was the most recent year complete data was available at the start of this survey (T. Daniel, personal correspondence, July 24, 2012). The resulting dataset included named facilities as well as categories such as 'home or other non-institution', 'clinic or Dr office', 'other institution' and 'out of state delivery'. Births recorded in these categories were not included as there was no way to identify a facility associated with the birth. A total of 94 facilities were identified, including those that only had a birth due to an emergency and were not considered to have official birthing facilities. Facilities were all sizes and spanned the state geographically.

The Nurse Manager or Nurse Supervisor for L & D was identified as the best potential survey respondent. In order to identify participants, the L & D department or in a few cases, the Emergency Department, was contacted and asked to identify the Nurse Manager/Supervisor for the L & D department. Then, either the call was transferred to the Nurse Manager's voicemail or the person answering the phone provided the direct number to call for the Nurse Manager. Multiple attempts were made to contact the Nurse Manager and voicemails were left requesting the person participate in the survey.

All 94 facilities were contacted, although only 84 (89%) email addresses were obtained in order to send the survey link. One facility refused to participate and other facilities did not

return calls although multiple attempts were made. Of the 10 facilities that did not return calls, 70% were facilities with 500 births or less in 2010. These facilities mostly represent locations where a birth occurred due to an emergency and do not normally have women deliver at their location. Also, of the 10 facilities that did not return calls, 60% were located in the Piedmont, with 40% located in Coastal counties. See Figure 4 for breakdown of geographical region by county. Of the 84 facilities where an email address was obtained, 61 participants completed the survey with 1 participant starting but not completing the survey.

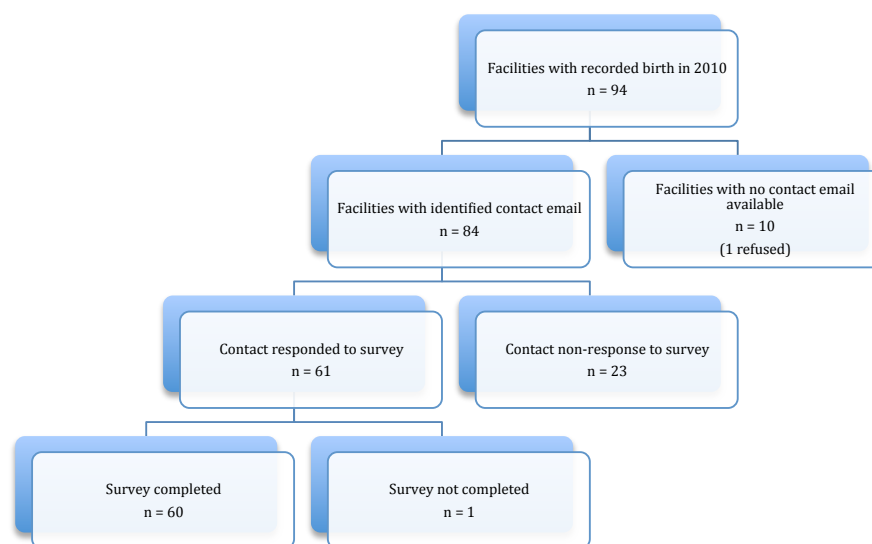


Figure 2 – Diagram of survey process

Survey Administration

The survey was developed and distributed online via SurveyMonkey. Persons noted on the acknowledgement page provided expertise in developing the survey questions to ensure the correct terminology as appropriate to L & D activities. Once the Nurse Manager's email address was obtained from a facility, they were added to the recipient list in the software

and a standard email was sent with a link to the survey. An initial email and reminder emails were sent in order to encourage participation. No incentives were offered to complete the survey.

To:	[Email]
From:	"ccrowley@email.unc.edu via surveymonkey.com" <member@surveymonkey.com>
Subject:	Requesting your participation in a survey regarding HIV Testing Practices at Labor and Delivery in North Carolina
Body:	<p>Hello,</p> <p>Thank you for taking the time to participate in this survey. My name is Christy Crowley and I am a Master's candidate at the UNC Chapel Hill School of Public Health. For my Master's project, I have proposed a survey to collect information regarding HIV testing practices for pregnant women at Labor and Delivery. This evaluation will provide an overview of current practices in North Carolina.</p> <p>Facilities were selected based on showing recorded births for the 2010 calendar year. Based on discussion with knowledgeable medical personnel, it was determined that the survey participants should be the Nurse Manager for Labor and Delivery. You are receiving this email because you were identified as this person or the closest representative at your facility.</p> <p>Your participation in completing this survey is greatly appreciated. The survey should take less than 10 minutes of your time and your responses will not be linked to you personally or your organization. If you have any questions, or feel that you are not the correct person to provide responses to this survey, please let me know.</p> <p>You can find this survey online by clicking the following link: https://www.surveymonkey.com/s.aspx</p> <p>Thank you in advance for your participation,</p> <p>Christy Crowley</p> <p>MPH candidate UNC Chapel Hill Gillings School of Public Health ccrowley@email.unc.edu https://www.surveymonkey.com/optout.aspx</p>

Figure 3 - Survey email requesting participation

Survey Content

The survey contained 22 questions designed to assess HIV testing practices at L & D. Questions 1 and 2 describe demographic characteristics of the facility and respondent, respectively. Questions 3 through 12 determine the availability of documentation of

previous HIV testing. Questions 13 through 17 solicit information on whether or not an HIV test is administered at L & D and how the test is processed. Questions 18 through 20 ask about referral practices for HIV+ women and babies. Questions 21 and 22 determine if facilities have formal policies on HIV testing at L & D. See Appendix 1 for the full survey.

Statistical Methods

This survey was designed to qualitatively explore how different facilities in the state conduct HIV testing activities at L & D since no uniform statewide policy exists. Basic analysis was conducted via SurveyMonkey and MS Excel to determine the proportion of responses to each survey question. In order to assess differences based on demographics, facilities were grouped by region: Mountains, Piedmont, Coastal.



Figure 4. North Carolina counties represented by Region

In addition, facilities were assessed based on the number of births they had in 2010. Facilities were grouped into 3 categories according to number of births: 1-500, 501-1500, and 1500+.

Results

As noted in the Methods section, 94 facilities were identified as having a birth recorded in 2010. Email addresses were obtained for 84 respondents and 61 of these respondents participated in the survey. Many of the questions allowed respondents to select multiple answers if applicable, so response rates may be over 100% for these questions. A number of the questions allowed for an 'other' response where the respondent could write in a response if they felt the answer choices were not adequate.

Facilities by Region										
Facilities	Total	Total %	Rec'd Email	Rec'd email %	No email	No email %	Responded	Responded %	No Response	No Response %
Coast	32	34.0%	28	33.3%	4	40.0%	19	31.1%	9	39.1%
Piedmont	44	46.8%	38	45.2%	6	60.0%	30	49.2%	8	34.8%
Mountains	18	19.1%	18	21.4%	0	0.0%	12	19.7%	6	26.1%
total	94		84		10		61		23	

Facilities by # of Births										
# of Births	Total	Total %	Rec'd Email	Rec'd email %	No email	No email %	Responded	Responded %	No Response	No Response %
1-500	34	36.2%	27	32.1%	7	70.0%	19	31.1%	8	34.8%
501-1500	35	37.2%	34	40.5%	1	10.0%	27	44.3%	7	30.4%
1500+	25	26.6%	23	27.4%	2	20.0%	15	24.6%	8	34.8%
total	94		84		10		61		23	

Figure 5. Data Tables describing survey participation by Region and # of Births

Demographics (2 questions)

In Question 1, respondents were asked to describe the type of facility where they work.

They were allowed to select as many answers as were applicable to the facility.

Approximately 56% of respondents indicated they worked at a public hospital and / or 49% worked for a 'not for profit' facility. Facilities in the Coastal region were most likely to select public hospital (47%) and not for profit (47%). Facilities with more than 1500 births were least likely to select public hospital (26%) and not for profit (23%).

Question 2 requested respondents indicate the length of time in their current position. A majority of the respondents (53%) indicated that they had been in their current position for greater than five years. Twenty-six percent had been in their position greater than one year, but less than two years. Eight percent had been in their position less than six months, 7% had been in their position greater than six months, but less than one year, and 7% had been in their position greater than two years, but less than five years. Respondents that had been in their position greater than five years would have been in their position when the 2009 implementation of mandatory Rapid HIV testing in NC went into effect.

Documentation of Previous Testing (10 questions)

The availability of prenatal records is key in determining previous HIV testing history. Since the NC law required Rapid HIV testing for women in L & D if they have an undocumented status, several questions were asked about the availability of prenatal records. Questions 3 through 6 attempt to determine availability of prenatal records for review at L & D. Question 3 asked how often the prenatal record is available, with respondents indicating that the prenatal record is always (25%) or almost always (72%) available when the woman presents for L & D. Three percent of respondents, all from the Coastal region, indicated a woman's prenatal record is never available. For Question 4, 93% of respondents indicated that a woman's prenatal record is always reviewed to determine if she had an HIV test during this pregnancy. Only 8% of respondents felt there are consistent barriers to having the HIV testing history available as asked in Question 5. Of the respondents indicating consistent barriers, 40% were from the Coastal region and 60%

were from the Piedmont region. For Question 5, 60% of respondents that answered yes to having consistent barriers were facilities with 1500+ births in 2010.

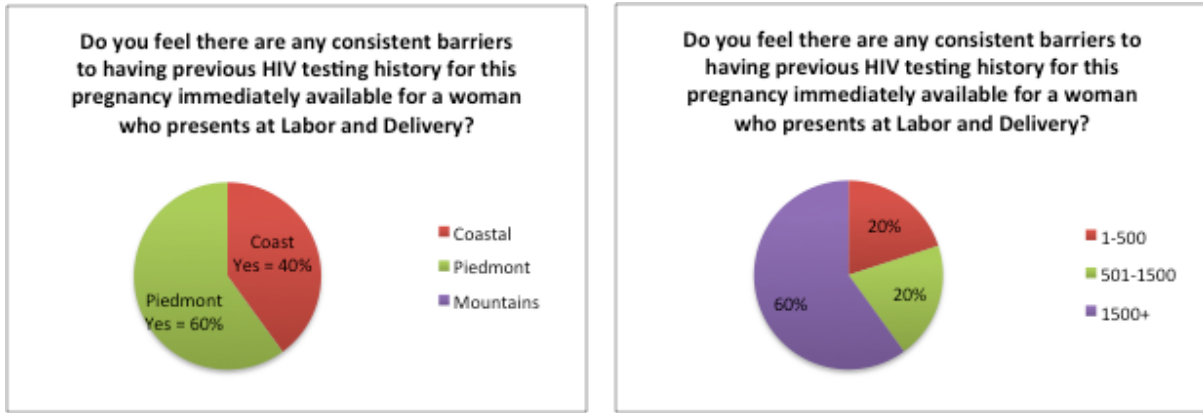


Figure 6. Survey Question 5, (left) % Responses by Region, (right) % Responses by # of Births

Question 6 allowed the respondent to select applicable barriers, which included 1) HIV test results not documented in the prenatal record; 2) prenatal records not transferred to L & D; 3) prenatal records not available for transport patient; 4) no electronic access to prenatal records; and 2 respondents chose to write-in responses. These responses were 'the HIV status just states consent signed, but results are not printed on the records that are faxed to us' and 'we are associated with a larger hospital and MDs only have access to records if that patient has prenatal care at the larger hospital. Otherwise, no prenatal record available'.

Questions 7 through 12 were designed to elicit responses regarding documentation of HIV testing and how the need for testing is communicated to the attending OB. In regards to Question 7, which asked about appropriate documentation, 66% of respondents indicated

that sufficient documentation that an HIV test was performed would be a copy of the laboratory results included with the woman's prenatal record. Another 53% indicated that an HIV test noted in the prenatal records would be sufficient documentation. Three percent of respondents did not know what would be considered sufficient documentation of HIV testing. The respondents who did not know were all from the Piedmont region and all at facilities with less than 500 births. Facilities with less than 500 births were also least likely to indicate that they included a copy of the laboratory results in the woman's prenatal record. No respondent selected patient self-report, which would not be considered a valid response. Two of the respondents selected to write-in an 'other' response that indicated that the Health Department has the lab results and does not make an actual copy available to the facility. Some local Health Departments do offer prenatal care, so it is possible that they are sending the prenatal record but not actual copies of lab results. The state Health Department should communicate to local Health Departments that including a copy of the lab results is a best practice.

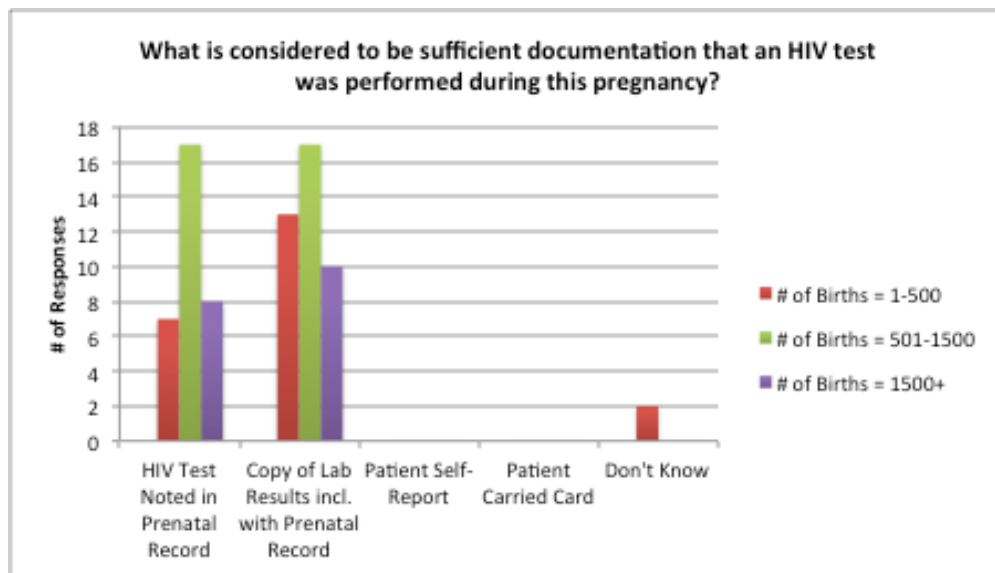


Figure 7. Survey Question 7, Responses by # of Births

Question 8 asked if the facility had a prenatal checklist, abstract, or some other means of summarizing a woman's information that is given to the attending OB. A checklist or abstract was used by 31% of facilities. Questions 9 and 10 allowed the respondent to indicate another method, which was used by approximately 51% of facilities. Facilities with less than 500 births were more likely to have a nurse review the prenatal record. Most of the 'other' responses as well as Question 11 indicated either that the OB reviews the charts personally or a nurse verbally communicates the chart information to the OB. Knowing that nursing staff may verbally communicate testing need is important because any education or training developed would need to be disseminated to both nursing staff as well as the OB's to ensure uniform practices. Question 11 allowed respondents to select multiple answers. Question 12 indicated that almost 92% of the time a woman's status is documented in the prenatal record.

HIV testing (5 questions)

Questions 13 through 17 discuss HIV testing at L & D. Based on responses to Question 13; an HIV test is always administered by 72% and almost always administered by 16% of facilities if no documentation is available. The answers 'sometimes' 'almost never' and 'never' were selected by approximately 12% of respondents. Therefore, a combined total of more than 27% of facilities are not uniformly testing women with undocumented HIV status at L & D. Two facilities selected 'never' and they are facilities that had less than 500 births in 2010. These responses indicate that some sort of education or training is needed to inform these facilities about their responsibilities to perform Rapid HIV testing as required by NC law.

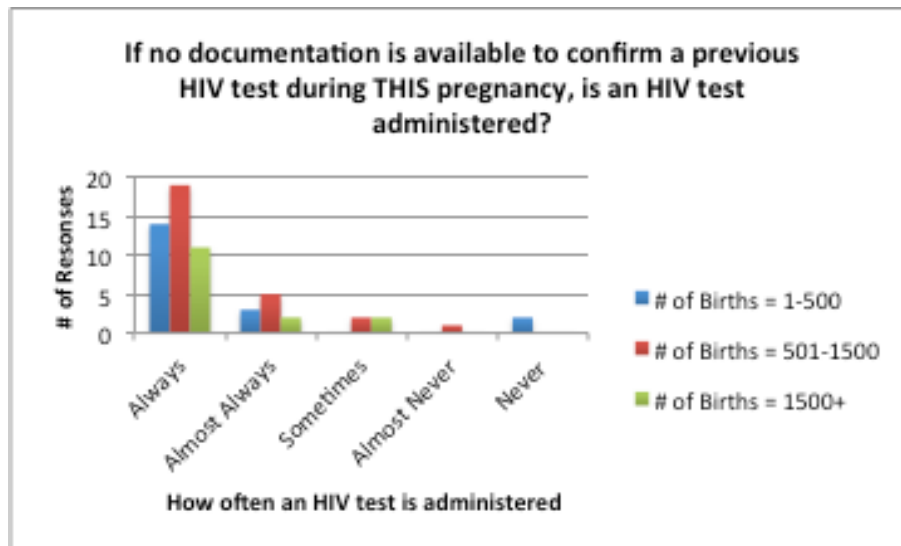


Figure 8. Survey Question 13, Responses by # of Births

Respondents were able to select more than one choice for Question 14 regarding when an HIV test would be administered. Intake (admissions) was selected by 76% of respondents,

while labor was selected by 53% of respondents. Approximately 12% of respondents indicated post-partum testing. Facilities in the Mountain region as well as facilities with 1500+ births were most likely to indicate post-partum testing. Note that testing post-partum represents a lost opportunity to provide short course antiretroviral therapy prior to delivery to reduce mother to child transmission. Question 15 asks about the location for processing an HIV test and allowed for more than one answer. Approximately 80% of respondents indicated that the test is processed in their hospital laboratory, with another 20% indicating the test is processed at an offsite laboratory. Multiple selections may indicate a Rapid HIV test done during labor with a follow up confirmatory test done at an offsite lab. This question may have been confusing to some respondents and perhaps should have been asked as two separate questions, distinguishing Rapid HIV testing from follow-up confirmatory testing. Confirmatory testing is often done at an offsite lab.

For Question 16, the amount of time for HIV test results to become available was 'less than 1 hour' (21%), 'greater than 1 hour, but less than 3 hours' (29%), 'greater than 3 hours, but less than 6 hours' (10%), greater than 12 hours, but less than 24 hours' (7%), 'greater than 24 hours' (7%) and 26% of respondents did not know the amount of time for HIV test results to become available. A combined total of 14% of facilities have wait times of greater than 12 hours, which may indicate that Rapid HIV tests are not being utilized. The respondents that did not know the amount of time for HIV results to become available were most likely in the Piedmont region and were facilities with more than 1500 births. Facilities in the Coastal region were most likely to report test result time of less than 1 hour.

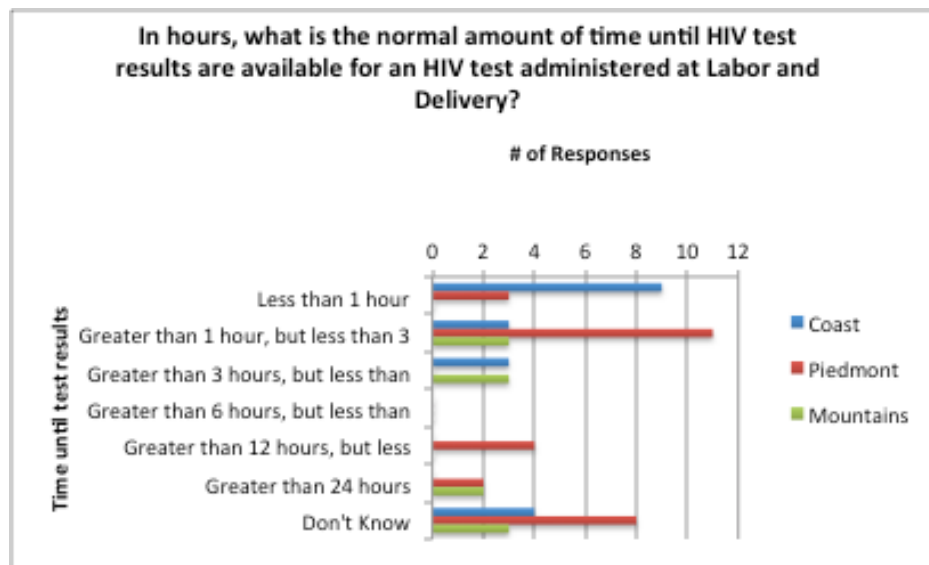


Figure 9. Survey Question 16, Responses by Region

Question 17 gave respondents an opportunity to list any reasons why a woman with undocumented status would not be tested. Lack of patient consent was selected by 34% of respondents. Other responses included no patient risk factors for HIV (5%); HIV testing not standard facility practice (3%), and infant will be tested after delivery (18%). None of these are valid barriers to testing, since NC law mandates testing, except in the case where the test can't be performed without endangering the patient. NC DHHS needs to provide education to facilities that emphasizes that the authority for testing at L & D resides with the attending L & D physician.

Referrals (3 questions)

Questions 18 through 20 asked if facilities provide referrals for HIV+ women and their newborns to a physician with expertise in treating HIV disease. Question responses indicate that women are referred approximately 45% of the time, while their infants were

referred approximately 53% of the time. A combined total of 25% of respondents did not know whether or not they provided referrals for women or their newborns. Only 46% of respondents referred patients to one of the five regional centers with expertise in treating HIV disease. Referring a woman and her newborn to an HIV disease specialist who can counsel against breastfeeding and continue the infant's post-exposure treatment also reduces the likelihood of HIV transmission from mother to child (Li & Sax, 2010). The CDC (2004) emphasizes the importance of referral to an HIV disease specialist to ensure the infant receives the appropriate care to interrupt perinatal transmission. A number of respondents chose to write-in an 'other' response to Question 20 indicating that they rely on the physician that provided the prenatal care to provide a referral to an HIV disease specialist. Although the NC law does not make specific provisions for referrals, continuing the infant's post-exposure treatment is of primary importance; therefore, NC DHHS should communicate to facilities that best practices should be that the mother and child are referred immediately after delivery.

Facility HIV policies (2 questions)

Formal HIV testing policies may improve the likelihood that a patient with an undocumented HIV status is tested at L & D (Levison, Williams, Moore, McFarlane, & Davila, 2011). Questions 20 and 21 determined if facilities had a formal policy describing the procedures required at L & D to determine if a woman has been tested for HIV during this pregnancy. Approximately 68% of respondents indicated their facility had a formal policy and 7% did not know if their facility had a policy or not. Of the facilities that did have a policy, 87% had a written policy. Most respondents knew whether or not their facility had

a formal policy. Although the numbers of referrals from Questions 18-20 seems quite low in comparison to the number of facilities that have testing policies, it is possible that a facility's testing policy does not include a referral to an HIV disease specialist since that is not specifically detailed in NC law.



Figure 10. Survey Question 21, Responses by # of Births

Conclusions / Recommendations

This survey supported the findings of a study by Anderson et al (2002) that providers may be confused about the need for consent for HIV testing. NC providers may not realize that for women with an undocumented HIV status at L & D consent is not required, but that Rapid HIV testing is required by NC law. This survey found that only 72% of survey respondents indicated that a woman with undocumented status at L & D would be tested for HIV.

If HIV testing was not done during prenatal care, then HIV testing should be performed as soon as possible at L & D, yet approximately 12% of respondents indicated that testing would be done post-partum. Wait times for test results exceeded 12 hours for 14% of facilities. Patient consent was selected as a reason for not testing by 34% of respondents. Other reasons not to test that were write-in reasons included 'not ordered by MD/Physician', 'we only perform emergency deliveries', 'if mother refuses then the baby is tested'.

Analysis conducted against survey results determined that facilities in the Coastal region had the highest non-response to the survey. In addition, Coastal and Piedmont regions were more likely to answer 'don't know' to questions. Respondents from the Coastal and Piedmont regions and those from facilities with more than 1500 births were more likely to indicate barriers to testing.

One strength of this study is the diverse set of participants. Respondents represented all sizes of facilities from all regions of NC. A limitation of this study is the reliance on self-report of the participants. Bias may have been incurred if respondents exaggerated answers in an effort to make their facility practices look better than they actually are. On the other hand, since respondents were assured that responses would not be linked to them or their facilities personally, they may have answered more accurately. An additional limitation is the potential that respondents may not have understood some of the survey questions as noted in the Results section. Another study limitation is that due to confidentiality requirements, survey results cannot be linked to individual facilities and thus neither can any efforts at education / training be targeted to specific facilities as applicable based on their responses. However, the survey hopefully served the purpose of “survey as education” and findings indicate that overall, NC facilities could benefit from NC DHHS sharing best practices or providing some training in this area.

Study results indicate that NC DHHS has a need to ensure that medical personnel understand their responsibilities for Rapid HIV testing women with undocumented status at L & D. Providers may be confused about the need for consent for HIV testing, Rapid HIV tests may not be the tests used, and immediate referral for positive mothers and newborns may not be the standard practice. A study of two county hospitals in Texas found that promoting change at the system level, rather than at the level of individual providers, provided the best results in increasing Rapid HIV testing (Levison, Williams, Moore, McFarlane, & Davila, 2011). Since developing formal policies at individual facilities can take time, the first recommendation would be for the NC DHHS to provide leadership at the

state level to develop model standards and a best practices document that provides a standard uniform policy and details how it can be adopted by NC facilities.

This best practices document should provide guidance in regards to confirming a woman's HIV status and conducting Rapid HIV testing at L & D when appropriate. As part of an organization's Quality Improvement (QI) measures, the Health Resources and Services Administration (HRSA) recommends creating a visual map of the care process known as a critical pathway (U.S. Department of Health and Human Services, Health Resources and Services Administration, 2011). This map provides the steps for delivery of care that walk applicable facility staff through the steps for ensuring Rapid HIV testing of pregnant women at L & D. Best practices should include recommending that facilities have standing admitting orders to conduct a Rapid HIV test on any woman with undocumented status at L & D. NC DHHS should develop a critical pathway that depicts the best practices for these activities. Figure 11 provides a sample critical pathway that might be used.

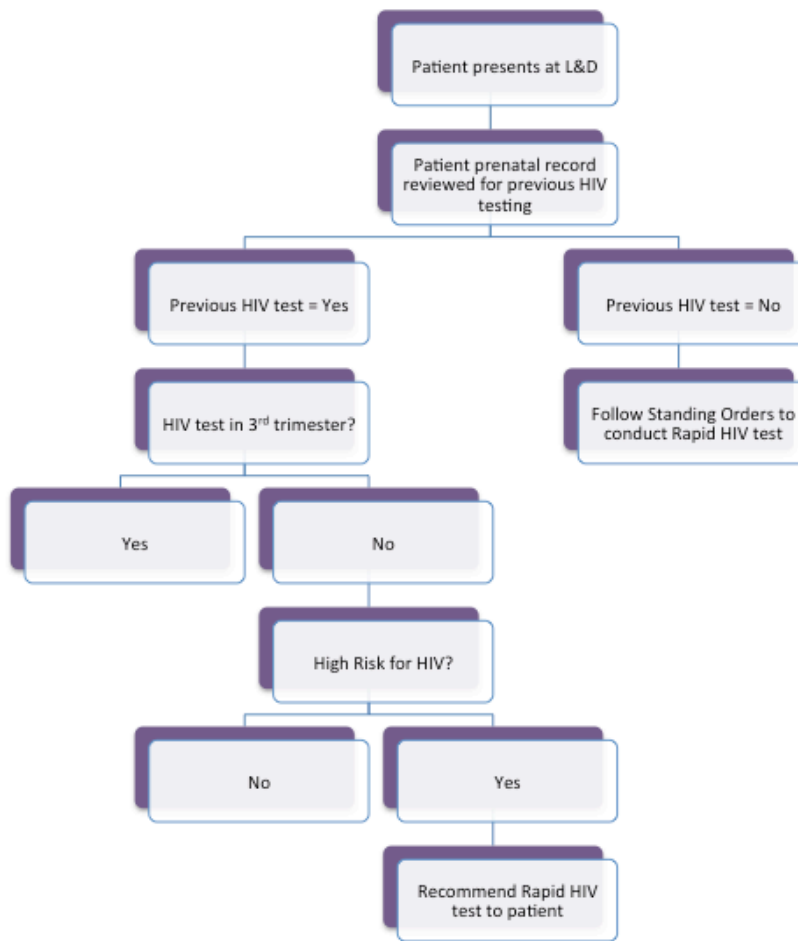


Figure 11. Sample suggested Critical Pathway for conducting Rapid HIV testing at Labor and Delivery

In addition to the best practices document to be disseminated to facilities, training should be developed to inform providers about NC law, the availability and benefits of Rapid HIV testing, and the need for mother and infant referral, particularly noting the existence of the five regional centers that specialize in HIV disease care. This training could be completed for continuing education credits in Nursing (CNE), and Medicine (CME for physicians and non-physicians). Offering continuing education credits may improve the likelihood that the training will be accessed. As noted in the survey, nursing staff are often key in providing

verbal/written reports to physicians and can identify the need for a test if status is not documented. Therefore, disseminating the training could be sponsored and provided in conjunction with the North Carolina Nurses Association (NCNA) as well as the NC Chapter of the American College of Obstetricians and Gynecologists (NC ACOG). ACOG already provides some materials such as a script for physicians to use to notify a patient about HIV screening (The American College of Obstetricians and Gynecologists, 2011). See Appendix 2 for the sample script.

NC DHHS should also confirm that facilities have access to Rapid HIV tests and if needed, provide guidance to facilities in obtaining and administering these tests. CDC recommends a needs assessment for facilities to determine if Rapid HIV testing should be conducted in the hospital laboratory or as point of care in the L & D unit (Centers for Disease Control and Prevention, 2004). CDC also provides information on the available types of Rapid HIV tests and purchasing details (Stanger, Margolin, Lampe, Clark, & Branson, 2008). See Appendix 3 and 4 for the spreadsheets CDC has available. NC DHHS should ensure that facilities are aware that patients who are insured with Medicaid and Medicare are eligible for three HIV screenings during pregnancy, including testing conducted at L & D (Centers for Medicaid and Medicare, 2011).

The goal of eliminating perinatal HIV transmission is possible to reach in North Carolina. The state law mandating Rapid HIV testing for undocumented women at L & D represents a final opportunity to stop perinatal transmission prior to delivery and provides the means to ensure that HIV status is known for all women prior to delivery or immediately

thereafter. Implementing uniform statewide best practices, educating providers on the law, and ensuring availability of Rapid HIV tests at every facility may allow NC to eliminate perinatal HIV transmission altogether.

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HIV Testing Practices at Labor and Delivery

1. Survey Instructions

Thank you for taking the time to complete this survey on HIV Testing Practices at Labor and Delivery. We are interested in learning more about how facilities determine if women at Labor and Delivery should be tested for HIV. The results from this survey will be used to develop an understanding of HIV testing practices at North Carolina Labor and Delivery facilities.

Your participation in this survey is completely voluntary and confidential. There are no anticipated risks from your participation in this survey. All data obtained from this survey will be reported for analysis only. The only person who will have access to these data is the investigator.

This survey should only take about 5-10 minutes of your time.

This survey is the final step towards completion of an MPH degree. If you have any questions about the survey, please contact Christy Crowley at ccrowley@email.unc.edu or 404-966-1464.

In order to progress through this survey, please use the following navigation buttons:

Click the Next button to continue to the next page.

Click the Previous button to return to the previous page.

Click the Exit the Survey Early button if you need to exit the survey.

Click the Submit button to submit your survey.

2. General Information

*1. How would you describe the type of facility at which you work? (Check all that apply)

☐ Teaching Hospital

☐ Public Hospital

☐ Private Hospital

☐ Clinic

☐ Birthing Center

☐ Not for Profit

☐ For Profit

☐ Other (please specify)

HIV Testing Practices at Labor and Delivery

2. How long have you been in your current job position at your facility?

- ☐ Less than 6 months
- ☐ Greater than 6 months, but less than 1 year
- ☐ Greater than 1 year, but less than 2 years
- ☐ Greater than 2 years, but less than 5 years
- ☐ Greater than 5 years

3. Prenatal Records

***3. When a woman presents at your facility for Labor and Delivery, how often is her outpatient prenatal record (for those who received prenatal care) available for review?**

- ☐ Always
- ☐ Almost Always
- ☐ Sometimes
- ☐ Almost Never
- ☐ Never

***4. When a woman presents at your facility for Labor and Delivery, if her prenatal record is available, is the record reviewed to determine if she had an HIV test during THIS pregnancy?**

- ☐ Always
- ☐ Almost Always
- ☐ Sometimes
- ☐ Almost Never
- ☐ Never

***5. Do you feel there are any consistent barriers to having previous HIV testing history for THIS pregnancy immediately available for a woman who presents for Labor and Delivery?**

- ☐ Yes
- ☐ No
- ☐ Not Sure
- ☐ Don't Know

HIV Testing Practices at Labor and Delivery

4. Prenatal Records

6. What are some consistent barriers to having previous HIV testing history for THIS pregnancy immediately available for a woman who presents for Labor and Delivery? (Check all that apply)

- ☐ HIV test results not documented in the prenatal record
- ☐ Prenatal records not transferred to Labor and Delivery
- ☐ Prenatal records are received but difficult to access in Labor and Delivery
- ☐ Prenatal records not always available on nights or weekends
- ☐ Prenatal record not available for transport patient
- ☐ No electronic access to prenatal records
- ☐ Prenatal record not legible
- ☐ Other Issues or comments (please specify)

***7. At your facility, what is considered to be sufficient documentation that an HIV test was performed during THIS pregnancy?**

- ☐ HIV test noted in prenatal records (no copy of lab results available)
- ☐ Copy of laboratory results included with prenatal record
- ☐ Patient self-report of HIV test
- ☐ Patient carried card
- ☐ Don't Know
- ☐ Other (please specify)

8. Does your facility have a staff member summarize a woman's prenatal record using a checklist / abstract that summarizes a woman's prenatal record and is given to the attending OB for Labor and Delivery?

- ☐ Yes
- ☐ No
- ☐ Don't Know

HIV Testing Practices at Labor and Delivery

5. Prenatal Records

***9. If your facility does not use a checklist / abstract to summarize a woman's prenatal record, is there another method by which her information is provided to the attending OB for Labor and Delivery?**

- ☐ Yes
- ☐ No
- ☐ Don't Know

6. Prenatal Records

***10. What other method is used to provide the information from a woman's prenatal record to the attending OB for Labor and Delivery?**

7. Prenatal Records

11. Who is responsible for completing this checklist / abstract / other method at your facility? (Check all that apply)

- ☐ Nurse
- ☐ OB
- ☐ Admissions Personnel
- ☐ Other (please specify)

***12. Does this checklist / abstract / other method indicate whether the woman had an HIV test during THIS pregnancy?**

- ☐ Yes
- ☐ No
- ☐ Don't Know

HIV Testing Practices at Labor and Delivery

***13. If no documentation is available to confirm a previous HIV test during THIS pregnancy, is an HIV test administered?**

- ☐ Always
- ☐ Almost Always
- ☐ Sometimes
- ☐ Almost Never
- ☐ Never

8. Prenatal Records

14. If an HIV test is administered for a woman at Labor and Delivery, when would the HIV test be administered? (Check all that apply)

- ☐ Intake
- ☐ Labor
- ☐ Delivery
- ☐ Post-Partum
- ☐ Don't Know
- ☐ Other (please specify)

15. If an HIV test is administered for a woman at Labor and Delivery, where is the HIV test processed for a result? (Check all that apply)

- ☐ In the hospital laboratory
- ☐ At an offsite laboratory
- ☐ Point of care test at Labor and Delivery
- ☐ Don't Know
- ☐ Other (please specify)

HIV Testing Practices at Labor and Delivery

16. In hours, what is the normal amount of time until HIV test results are available for an HIV test administered at Labor and Delivery?

- ☐ Less than 1 hour
- ☐ Greater than 1 hour, but less than 3 hours
- ☐ Greater than 3 hours, but less than 6 hours
- ☐ Greater than 6 hours, but less than 12 hours
- ☐ Greater than 12 hours, but less than 24 hours
- ☐ Greater than 24 hours
- ☐ Don't Know

***17. What are the reasons why an HIV test would not be administered, if no documentation is available that confirms a previous HIV test? (Check all that apply)**

- ☐ Inadequate time to perform test prior to delivery
- ☐ Inadequate time to receive test results prior to delivery
- ☐ Patient does not have risk factors for HIV
- ☐ Patient does not consent to HIV test
- ☐ HIV testing not standard facility practice
- ☐ Point of Care / Rapid testing not available
- ☐ HIV test will be administered to infant post-delivery
- ☐ Don't Know
- ☐ Other (please specify)

9. Policies and Procedures

18. Does your facility have specific policies or procedures to refer women who test HIV positive at Labor and Delivery to a physician with expertise in treating HIV disease?

- ☐ Yes
- ☐ No
- ☐ Don't Know

HIV Testing Practices at Labor and Delivery

19. Does your facility have specific policies or procedures to refer HIV-exposed newborns to a physician with expertise in treating pediatric HIV disease?

- ☐ Yes
- ☐ No
- ☐ Don't Know

20. If your facility refers HIV+ women or HIV-exposed newborns to a physician with expertise in treating HIV disease, where is this physician located?

- ☐ Carolinas Medical Center
- ☐ Duke University Medical Center
- ☐ ECU / Vidant Health Care
- ☐ UNC / New Hanover Health Center
- ☐ Wake Forest Health Sciences
- ☐ No Referral made
- ☐ Don't Know

Other (please specify)

***21. Does your facility have a policy that describes the procedures required at Labor and Delivery to determine if a woman has been tested for HIV during THIS pregnancy?**

- ☐ Yes
- ☐ No
- ☐ Don't Know

10.

22. If your facility has a policy regarding HIV testing for women at Labor and Delivery, is this policy:

- ☐ Written
- ☐ Verbal
- ☐ Both Written and Verbal
- ☐ Don't Know

Physician Script on Perinatal HIV Screening



All pregnant women should be screened for human immunodeficiency virus (HIV) infection as early as possible during each pregnancy. Human immunodeficiency virus screening should occur after the patient is notified that the screening is recommended for all pregnant women and that she will receive the test as part of the routine panel of prenatal tests unless she declines (opt-out screening). Pregnant women should be provided with oral or written information about HIV that includes an explanation of HIV infection, a description of interventions that can reduce HIV transmission from mother to infant, the meanings of positive test results and negative test results, and the opportunity to ask questions and decline testing. No additional process or written documentation of informed consent, beyond what is required for other routine prenatal tests, is required for HIV testing, unless state legal requirements necessitate additional documentation. A repeat test in the third trimester is recommended for women at high risk of acquiring HIV; however, some states require a repeat test later in pregnancy for all pregnant women. Obstetrician–gynecologists should be aware of and comply with their states' legal requirements for perinatal HIV screening. Legal requirements for perinatal HIV testing may be verified by contacting state or local public health departments or at www.nccc.ucsf.edu (also see Resources). If a patient declines HIV testing, it should be documented in the medical record and should not affect access to care. She also should be reoffered testing at a subsequent visit.

When notifying pregnant patients about HIV screening in states using opt-out screening, obstetric providers may find it helpful to preface the conversation with the following suggested script:

"I test all my pregnant patients for HIV as part of the panel of routine tests to alert me to any conditions that require regular attention or treatment to promote the best possible outcome in pregnancy. You also may need a repeat HIV test in the third trimester. This patient information, *HIV and Other Important Pregnancy Tests*, will explain the importance of each test. When you have finished reading this information, I would be glad to answer any questions you have. You will be tested for HIV today unless you tell me not to."

(see reverse)

To assist obstetric providers with prenatal HIV screening, the American College of Obstetricians and Gynecologists offers a Patient Education Pamphlet, HIV and Pregnancy, and the enclosed HIV and Other Important Pregnancy Tests, a convenient-to-use tear pad describing in simple language the recommended blood tests for all pregnant women. This tear pad also answers frequently asked questions about HIV testing, treatment, and risks for exposed babies. Obstetric providers may use the tear pad to help notify pregnant women about HIV testing, but used alone, the information in the tear pad may not meet informed consent requirements in individual states.

Resources

The American College of Obstetricians and Gynecologists
409 12th Street SW, PO Box 96920
Washington, DC 20090-6920
800-673-8444 or 202-638-5577
www.acog.org
HIV web site: www.womenandhiv.org

The National HIV/AIDS Clinicians' Consultation Center at the University of California –San Francisco maintains an online compendium of state HIV testing laws that can be a useful resource (www.nccc.ucsf.edu).

Location/Overnight Address: National HIV/AIDS Clinicians' Consultation Center
UCSF Department of Family and Community Medicine at San Francisco General Hospital
1001 Potrero Ave., Bldg. 20, Ward 22
San Francisco, CA 94110
Mailing Address:
UCSF Box 1365
San Francisco, CA 94143-1365
415-206-8700
Perinatal HIV Hotline: 1-888-448-8765
www.nccc.ucsf.edu

Centers for Disease Control and Prevention
1600 Clifton Road NE
Atlanta, GA 30333
www.cdc.gov/hiv

Downloadable resources for patients are available at
www.cdc.gov/hiv/resources/brochures/index.htm

FDA-Approved Rapid HIV Antibody Screening Tests

Appendix 3

February 4, 2008

	<u>FDA Approval Received</u>	<u>Specimen Type</u>	<u>CLIA Category*</u>	<u>Sensitivity** (95% CI)</u>	<u>Specificity** (95% CI)</u>	<u>Manufacturer</u>	<u>Approved for HIV-2 Detection?</u>	<u>List Price Per Device[^]</u>	<u>External Controls</u>
OraQuick ADVANCE Rapid HIV-1/2 Antibody Test	Nov 2002	Oral fluid	Waived	99.3% (98.4-99.7)	99.8% (99.6-99.9)	OraSure Technologies, Inc. www.orasure.com	Yes	\$17.50	Sold Separately (\$25 each)
		Whole Blood (finger stick or venipuncture)	Waived	99.6% (98.5-99.9)	100% (99.7-100)				
		Plasma	Moderate Complexity	99.6% (98.9-99.8)	99.9% (99.6-99.9)				
Uni-Gold Recombigen HIV	Dec 2003	Whole blood (fingerstick or venipuncture)	Waived	100% (99.5-100)	99.7% (99.0-100)	Trinity Biotech www.unigoldhiv.com	No	\$15.75 \$8.00 [■]	Sold Separately (\$26.25 each)
		Serum & Plasma	Moderate Complexity	100% (99.5-100)	99.8% (99.3-100)				
Reveal G-3 Rapid HIV-1 Antibody Test	Apr 2003	Serum	Moderate Complexity	99.8% (99.2-100)	99.1% (98.8-99.4)	MedMira, Inc. www.medmira.com	No	\$14.00	Included
		Plasma	Moderate Complexity	99.8% (99.0-100)	98.6% (98.4-98.8)				

■ "Public health" price for public health programs that are recipients of CDC funds for expanded HIV testing

* Clinical Laboratory Improvement Amendments: CLIA regulations identify three categories of tests: waived, moderate complexity, or high complexity
 ** Sensitivity is the probability that the test result will be reactive if the specimen is a true positive; specificity if the probability that the test result will be nonreactive if the specimen is a true negative. Data are from the FDA summary basis of approval, for HIV-1 only. For HIV-2 information, see package inserts.
 ^ Actual price may vary by purchasing agreements with manufacturers

Note: Trade names are for identification purposes only and do not imply endorsement. This information was compiled from package inserts and direct calls to manufacturers.

FDA-Approved Rapid HIV Antibody Screening Tests

February 4, 2008

	<u>FDA Approval Received</u>	<u>Specimen Type</u>	<u>CLIA Category**</u>	<u>Sensitivity** (95% CI)</u>	<u>Specificity** (95% CI)</u>	<u>Manufacturer</u>	<u>Approved for HIV-2 Detection?</u>	<u>List Price Per Device[^]</u>	<u>External Controls</u>
MultiSpot HIV-1/HIV-2 Rapid Test	Nov 2004	Serum	Moderate Complexity	100% (99.94-100)	99.93% (99.79-100)	BioRad Laboratories www.biorad.com	Yes – differentiates HIV-1 from HIV-2	\$25.00	Included
		Plasma	Moderate Complexity	100% (99.94-100)	99.91% (99.77-100)				
Clearview HIV 1/2 STAT-PAK	May 2006	Whole Blood (finger stick or venipuncture)	Waived	99.7% (98.9-100)	99.9% (99.6-100)	Inverness Medical Professional Diagnostics www.invernessmedicalpd.com	Yes	\$17.50 \$8.00 [■]	Sold Separately (\$50/set)
		Serum & Plasma	Non-waived	99.7% (98.9-100)	99.9% (99.6-100)				
Clearview COMPLETE HIV 1/2	May 2006	Whole Blood (finger stick or venipuncture)	Waived	99.7% (98.9-100)	99.90% (99.6-100)	Inverness Medical Professional Diagnostics www.invernessmedicalpd.com	Yes	\$18.50 \$9.00 [■]	Sold Separately (\$50/set)
		Serum & Plasma	Non-waived	99.7% (98.9-100)	99.9% (99.6-100)				

■ “Public health” price for public health programs that are recipients of CDC funds for expanded HIV testing

* Clinical Laboratory Improvement Amendments: CLIA regulations identify three categories of tests: waived, moderate complexity, or high complexity

** Sensitivity is the probability that the test result will be reactive if the specimen is a true positive; specificity if the probability that the test result will be nonreactive if the specimen is a true negative. Data are from the FDA summary basis of approval, for HIV-1 only. For HIV-2 information, see package inserts.

[^] Actual price may vary by purchasing agreements with manufacturers

Note: Trade names are for identification purposes only and do not imply endorsement. This information was compiled from package inserts and direct calls to manufacturers.

FDA-Approved Rapid HIV Antibody Screening Tests – Purchasing Details

Appendix 4

February 4, 2008

	<u>Price Per Device*</u>	<u>External Controls</u>	<u># of Tests per Case</u>	<u>Catalog numbers</u>	<u>Storage Temperature</u>	<u>Operating Temperature</u>	<u>Shelf life of Test**</u>	<u>Shelf Life of Control**</u>	<u>Total Time Required to Conduct Test***</u>	<u>Window Period for Reading Results****</u>
OraQuick ADVANCE Rapid HIV-1/2 Antibody Test www.oraasure.com	\$17.50	Sold Separately (\$25)	25 or 100	#1001-0079 (25 tests) #1001-0078 (100 tests) #1001-0077 (controls)	2-27°C (tests) 2-8°C (controls)	15-37°C	6 months	12 months 21 days (after opening)	<5 minutes (<10 min. for plasma)	20-40 min
									+ 20 min wait time	
Uni-Gold Recombigen HIV www.unigoldhiv.com	\$15.75 \$8.00-	Sold Separately (\$26.25)	20	#1206506 (tests) #1206530 (controls)	2-27 °C (tests) 2-8 °C (controls)	15-27°C	12 months	12 months 1 month (after opening)	<5 minutes	10-12 min
									+ 10 min wait time	
Reveal G-3 Rapid HIV-1 Antibody Test www.reveal-hiv.com	\$14.00	Included	20 or 60	B1057-6 (20 test kits) B1057-7 (60 test kits)	2-30°C (tests) 2-8°C (controls)	15-27°C	12 months	12 months 7 days (after reconstituting)	3-5 minutes	Result must be read immediately
									No add. wait time	

▪ “Public health” price for public health programs that are recipients of CDC funds for expanded HIV testing

* Actual price may vary by purchasing agreements with manufacturers

** From date of manufacture, unless otherwise noted

*** First time listed is estimated time required to set up test. The second time is the required wait time before reading results. Times listed exclude time needed to draw/obtain sample

**** As measured from last step of testing process

Note: Trade names are for identification purposes only and do not imply endorsement. This information was compiled from package inserts and direct calls to manufacturers.

FDA-Approved Rapid HIV Antibody Screening Tests – Purchasing Details

February 4, 2008

	<u>Price Per Device*</u>	<u>External Controls</u>	<u># of Tests per Case</u>	<u>Catalog numbers</u>	<u>Storage Temperature</u>	<u>Operating Temperature</u>	<u>Shelf life of Test**</u>	<u>Shelf Life of Control**</u>	<u>Total Time Required to Conduct Test***</u>	<u>Window Period for Result Validity****</u>
MultiSpot HIV-1/HIV-2 Rapid Test www.biorad.com	\$25.00	Included	50	#72269 (test kits)	2-8 °C Or 20-30 °C (tests and controls)	20-30°C	12 months (@ 2-8 °C) 3 months (@ 20-30 °C)	12 months	10-15 minutes No add. wait time	Can be read immediately or anytime up to 24 hours
	\$17.50 \$8.00-	Sold Separately (\$50/set)	20 per kit	92110 (tests) 92112(controls)	8-30°C or 46-86°F	18-30°C or 64-86°F	24 months	24 months	< 5 minutes + 15 min wait time	15-20 minutes
Clearview HIV 1/2 STAT-PAK <a href="http://www.invernessmedi
calpd.com">www.invernessmedi calpd.com	\$18.50 \$9.00-	Sold Separately (\$50/set)	25 per kit	92111 (tests) 92112 (controls)	8-30°C or 46-86°F	18-30°C or 64-86°F	24 months	24 months	< 5 minutes + 15 min wait time	15-20 minutes

▪ “Public health” price for public health programs that are recipients of CDC funds for expanded HIV testing

* Actual price may vary by purchasing agreements with manufacturers

** From date of manufacture, unless otherwise noted

*** First time listed is estimated time required to set up test. The second time is the required wait time before reading results. Times listed exclude time needed to draw/obtain sample

**** As measured from last step of testing process

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